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REPLY MEMORANDUM AND AUTHORITIES

I. INTRODUCTION

In NVT's Opposition To NITEK's Motion To Dismiss for lack of subject matter jurisdiction ("NVT's Opposition"), NVT argues that NITEK's actions "have created uncertainty in the competitive environment." Without pointing to any competent facts to support that "uncertainty," NVT asserts that there is an actual controversy based upon "the standard set forth in the *MedImmune*, v. *Genentech*, 127 S. Ct. 764 (2007) and the Federal Circuit cases that follow." NVT's Opposition, Pg. 1, ll. 10-12. NVT's reliance on *MedImmune* and the Federal Circuit cases that follow is misplaced at least because NITEK did not do anything to create a controversy, notwithstanding NVT's attempt to color the facts in an attempt to concoct an actual controversy. It is undisputed that NITEK never directly or indirectly threatened NVT with suit for infringement. NITEK never told anyone that it would enforce its patent against NVT. NITEK never asserted rights under its patent based upon any identified activity of NVT. NITEK never stated that NVT needed a license either to avoid an infringement suit or otherwise (the license offer was at the request of NVT in an attempt to settle NVT's previous declaratory judgment lawsuit). NITEK never created any controversy with NVT relating to NITEK's patent.¹

In fashioning a controversy, NVT largely relies on its own purely subjective fear and the announcement via a press release of issuance of NITEK's patent. Beyond that, NVT mischaracterizes actions of a third party (Anixter) and attributes those actions, if they even occurred, to NITEK in its effort to create a controversy where there is none. The acts upon which NVT relies in attempting to fashion its case or controversy are hypothetical at best and in any event are not actions of NITEK. NITEK has taken no actions whatsoever to assert any concrete right in any adverse manner against NVT.

¹ It may be of some import for the Court to take official notice that NITEK has never sued anyone for infringement of its `149 patent at issue in this case. In fact, NITEK has never sued anyone for infringement of any patent. Gerstman Decl., Ex.5, ¶ 18.

NVT improperly urges this Court to accept Judge Matz's finding of an actual controversy but to reject Judge Matz's dismissal of a similar case filed in the Central District of California on basically the same facts. NITEK respectfully submits that Judge Matz's finding of an actual controversy was erroneous as it was made without the benefit of recent Federal Circuit case law giving guidance as to proper analyses for determining subject matter jurisdiction in patent cases under the Declaratory Judgment Act post-*MedImmune*. Rightly, Judge Matz was at best uncertain about his finding of subject matter jurisdiction, stating that he "erred on the side of finding there is" an actual controversy (Tr., p. 7).² He referred to the actual controversy as "this marginally [sic — marginal"] actual controversy" (Tr., p. 5); he also referred to the actual controversy as "weak." (Tr., p. 8). This Court should readily see that the facts alleged, under all the circumstances, do not "show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, supra*, 127 S. Ct. at 771.

NVT suggests that Judge Matz dismissed the case because he believed it was more properly brought in this forum. However, Judge Matz had many reasons for declining to proceed which had nothing to do with the particular forum. He recognized that NVT wanted to get the tactical advantage of moving first, of squeezing NITEK and obtaining immunity by demanding a covenant not to sue (Tr., pp. 4-5). He also recognized that there were "no threats that the defendant had directly issued at all." (Tr., p. 5) He stated that NITEK's press release was "kind of innocuous and not focused on this plaintiff at all." (*Id.*) He also recognized that NITEK had made assurances that it had no intent to sue. (*Id.*) He stated that the declaration filed by NVT's president Nitzan "doesn't speak in any persuasive manner or about the existence of an actual

² The transcript of Judge Matz's hearing on NITEK's Motion To Dismiss the Central District of California Declaratory Judgment action brought by NVT against the `149 patent is Exhibit 2 to Defendant Nitek International LLC'S Notice Of Motion And Motion To Dismiss Complaint For Lack Of Subject Matter Jurisdiction Under F.R.C.P. 12(B)(1) ("NITEK's Motion To Dismiss"). Judge Matz did not issue an order dismissing the Central District action so the parties hereto must rely on the hearing transcript. References to the transcript are cited herein as "Tr., p. ___."

³ A copy of the *Prasco* decision is attached hereto as Reply Exhibit A.

controversy." (Tr., p. 6) He recognized that Nitzan's declaration "is pretty weak authority for the notion that there is an actual controversy." (*Id.*) He also recognized that there is no evidence that anyone has refused to do business with NVT or that anything that NVT is in a position to pursue has actually been undermined or compromised. (*Id.*) These numerous reasons, coupled with Judge Matz's belief that even if there were an actual controversy it would be marginal or weak, gave him more than enough discretionary reasons to dismiss the complaint.

II. UNDER ALL THE CIRCUMSTANCES THERE IS NO CONTROVERSY, ESPECIALLY IN VIEW OF RECENT FEDERAL CIRCUIT LAW

A. Purely Subjective Fear and the Mere Existence of a Potentially Adverse Patent Do Not Create a Controversy.

To the extent that NVT deems there to be "uncertainty in the competitive environment" (NVT's Opposition, pg. 1, II. 16-18) that perception is NVT's alone. NVT has not pointed to a single fact that supports any concerns "in the competitive environment," nor that justify its subjective fear. The Federal Circuit recently analyzed subject matter jurisdiction under the Declaratory Judgment Act in *Prasco*, *LLC v. Medicis Pharm. Corp.*, 2008 U.S. App. LEXIS 17329 (Fed. Cir. 2008).³

Under the facts of *Prasco*, the Federal Circuit affirmed dismissal for lack of subject matter jurisdiction of a declaratory judgment action asserting non-infringement of certain patents. *Id.* at *2. The Federal Circuit focused on the totality of the circumstances and found that *Prasco* had not alleged a controversy of sufficient "immediacy and reality" to create a justiciable controversy. *Id.* at *4. The Federal Circuit reviewed the facts from a "standing" perspective and stated that "to satisfy standing, the plaintiff must allege (1) an injury-in-fact, i.e., a harm that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical,' (2) that is 'fairly traceable' to the defendant's conduct, and (3) redressable by a favorable decision. [citations omitted]. Absent an injury-in-fact fairly traceable to the patentee, there can be no immediate and real controversy." *Id.* at *14-15.

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In *Prasco*, as is the case here, the declaratory judgment defendant had not issued a per se threat of suit by letter or otherwise, i.e. there was no charge of infringement. Rather the defendant merely marked its product with the applicable patent number (in the case at bar NITEK merely issued an innocuous press release announcing the issuance of its patent). The Federal Circuit provided that "*MedImmune* does not change our long-standing rule that the existence of a patent is not sufficient to establish declaratory judgment jurisdiction." *Id.* at *16; see also *Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed. Cir. 2004) ("More is needed than knowledge of . . . an adversely held patent."). The mere existence of a potentially adverse patent does not cause an injury nor create an imminent risk of an injury; absent action by the patentee, "a potential competitor . . . is legally free to market its product in the face of an adversely-held patent." *Teva Pharm. v. Novartis Pharm.*, 482 F.3d 1330, 1345 (Fed. Cir. 2007). *Prasco, supra,* 2008 LEXIS 17329 at *16.

Prasco argued that a case or controversy had nevertheless been created because it had suffered actual harm in the form of "paralyzing uncertainty" from fear that Medicis would bring an infringement suit against it. *Id.* at *16-17. NVT's "uncertainty in the competitive environment" in the present case is virtually the same as *Prasco's* "paralyzing uncertainty." The Federal Circuit found such "uncertainty" to be subjective apprehension, and pointed out that,

the Supreme Court has emphasized that a fear of future harm that is only subjective is not an injury or threat of injury caused by the defendant that can be the basis of an Article III case or controversy. City of L.A. v. Lyons, 461 U.S. 95, 103 S. Ct. 1660, 75 L. Ed. 2d 675 (1983); see also Indium Corp. of Am. v. Semi-Alloys, Inc., 781 F.2d 879, 883 (Fed. Cir. 1985) ("A purely subjective apprehension of an infringement suit is insufficient to satisfy the actual controversy requirement."). Rather, "it is the reality of the threat of . . . injury that is relevant to the standing inquiry, not the plaintiff's subjective apprehensions." City of L.A. v. Lyons, 461 U.S. at 107 n.8 (emphasis in original); see also Laird v. Tatum, 408 U.S. 1, 13-14, 92 S. Ct. 2318, 33 L. Ed. 2d 154 (1972) ("Allegations of a subjective 'chill' are not an adequate substitute for a claim of specific present objective harm or a threat of specific future harm; 'the federal courts established pursuant to Article III of the Constitution do not render advisory opinions."). Although MedImmune clarified that an injury-in-fact sufficient to create an actual controversy can exist even when there is no apprehension of suit, it did not change the bedrock rule that a case or controversy must be based on a real and immediate injury or threat of future injury that is caused by the defendants--an objective standard that cannot be met by a purely subjective or speculative fear of future harm. Thus, as we explained post-MedImmune, "jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without

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some affirmative act by the patentee." SanDisk Corp. v. STMicroelectronics, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007); *Prasco* at *17-18.

In *Prasco*, as here, the declaratory judgment plaintiff demanded a covenant not to sue, which was refused by the declaratory judgment defendant. In *Prasco*, the alleged "uncertainty" was far greater than any "uncertainty" that NVT may believe it has. *Prasco* had previously been sued by the declaratory judgment defendant Medicis on a different cleanser product covered by another Medicis patent. Here, the declaratory judgment defendant NITEK has never sued anyone on any patent.

Summarizing, the Court of Appeals in *Prasco* stated:

Here, where Prasco has suffered no actual present injury traceable to the defendants, and the defendants have not asserted any rights against Prasco related to the patents nor taken any affirmative actions concerning Prasco's current product, one prior suit concerning unrelated patents and products and the defendants' failure to sign a covenant not to sue are simply not sufficient to establish that Prasco is at risk of imminent harm from the defendants and that there is an actual controversy between the parties of sufficient immediacy and reality to warrant declaratory judgment jurisdiction. Although we understand Prasco's desire to have a definite answer on whether its products infringe defendants' patents, were the district court to reach the merits on this case, it would merely be providing an advisory opinion. This is impermissible under the Article III. Prasco at *26-27.

NVT can point to no "affirmative act by the patentee" to support jurisdiction. *Ibid*. The Federal Circuit has made it abundantly clear in *Prasco* that "there can be no controversy without a showing that this threat was real, imminent, and traceable to defendants [NITEK in this case].⁴ *Id.* at *19.

⁴ Contrary to NVT's repeated argument that "the old 'reasonable apprehension of suit' standard no longer applies after MedImmune" (NVT's Opposition, pg. 10, ll. 21-23, emphasis in original), it is of interest to note from *Prasco* that the Federal Circuit held otherwise stating that "While the Supreme Court rejected the reasonable apprehension of suit test as the sole test for jurisdiction, it did not completely do away with the relevance of a reasonable apprehension of suit. Rather, following *MedImmune*, proving a reasonable apprehension of suit is one of multiple ways that a declaratory judgment plaintiff can satisfy the more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy." Prasco at *10. NVT can not possibly allege on these facts that it has a reasonable apprehension of suit so its preference,

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⁵ The press release was a single press release but NVT asserts it as 3 separate points of controversy, emphasizing that: 1) it was written by NITEK's founder and stated what the patent covers; 2) it was sent as a "targeted" e-mail describing the patent rights; and 3) it was sent directly to customers).

D. NITEK Did Not State That it Intended to Enforce the '149 Patent Against NVT.

Relying on double hearsay, NVT claims that NITEK informed NVT's sales representatives at a trade show that NITEK was going to enforce the '149 patent against competitors such as NVT. In NITEK's Motion to Dismiss, section IV(B)(2), NITEK sets forth numerous arguments, and first hand declarations of fact from the only three NITEK employees at the trade show, debunking the lack of veracity of NVT's assertions. Again, NVT disputes none of those arguments. Amazingly, NVT simply ignores all of NITEK's declarations and in NVT's Opposition it repeats its allegations that are based on rank hearsay and are shown to be false by NITEK's direct declarations made by the only NITEK people who attended the trade show. NVT's disregard of NITEK's declarations and use of rank hearsay in an attempt to contradict the declarations is indicative of the veracity of NVT's position.

E. Competition Between NVT and NITEK Does Not Create a Controversy.

NVT points out in its argument that NVT competes with NITEK in the sale of products for transmitting CCTV over UTP cabling. NVT's Opposition, pg. 3, ll. 8-26. The fact that NVT and NITEK make competing products does not create an actual controversy where NITEK has never asserted that NVT products infringe NITEK's '149 patent. NVT can cite to no authority whatsoever to support its contention, and it should be readily appreciated that an actual controversy is certainly not created merely because a competitor sells products that compete with a patent owner's products, even if the competing products could potentially be used in a patented system. Review of the '149 patent specification and claims makes clear that it does not cover a particular product - - instead it covers a CCTV "system" for interfacing with a structured cabling system of a building. NVT's Opposition, Ex. 1.

In merely claiming to be a "competitor" of NITEK in the sale of UTP related products, NVT ignores the claims of the `149 patent and the fact that those claims are system claims. NVT ignores the fact that its products would have to be combined with other components in the particular configuration recited in the `149 patent claims in order to infringe those claims. Nowhere, in its submissions in this action or in the prior action has NVT ever articulated how its

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products are combined or might be combined to infringe the `149 patent claims. In making this argument NVT highlights the fact that its fear of suit is purely subjective, and that its declaratory judgment action improperly relies on a hypothetical state of facts.

F. NITEK's License Proposal Was For Settlement Purposes in Response To **NVT's Counsel's Request.**

Astonishingly, NVT attempts to support its argument for the existence of a controversy by referring to NITEK's offer to license the '149 patent to NVT after NVT sued NITEK in the Central District. Not surprisingly though, NVT omits the real story. Prior to service of the declaratory judgment complaint in the earlier case, NVT's counsel advised NITEK that a declaratory judgment suit had been filed against NITEK but that the action would be dismissed if NITEK would provide NVT with a covenant not to sue. See Motion to Dismiss, Ex. C to Gerstman Decl., Ex. 5., NVT Counsel Gary A. Hecker's August 24, 2008 letter to Edward L. Polanek. Obviously, NVT's purpose in filing the declaratory judgment action against NITEK was to coerce NITEK to give NVT a blanket covenant not to sue -- the equivalent of a perpetual royalty free license under the '149 patent.

Shortly thereafter, Attorney George Gerstman, counsel for NITEK, telephoned NVT's counsel and advised that there was no basis upon which to file a declaratory judgment suit and that certainly NITEK was not going to give NVT a perpetual royalty free license. However, at the request of NVT's counsel Gary A. Hecker, NITEK's counsel prepared a non-exclusive license for submission to NVT in order to have the lawsuit dismissed and to accommodate NVT. Although at no time did NITEK or its counsel in any way indicate to NVT that NVT had a need for a license, the license was requested by NVT's counsel so it was prepared and sent as a "RULE 408 OFFER TO COMPROMISE" at NVT's request. See, NITEK's Motion to Dismiss, Gerstman Decl., Ex. 12.

All of the foregoing discussion concerning the circumstances of the license was set forth in NITEK's Motion to Dismiss and none of it has been disputed by NVT. However, NVT disingenuously argues that the proposed license agreement required that NVT pay NITEK a ten percent royalty "in order for NVT to avoid a patent infringement claim by NITEK." This is

simply not true. The proposed license was solely for the purpose of settling the lawsuit and to accommodate NVT (and was offered at NVT's request). It was expressly sent as a "RULE 408 OFFER TO COMPROMISE." Not only was there never a patent infringement assertion by NITEK against NVT, but in Mr. Gerstman's August 24 letter, accompanying the proposed license, it was expressly stated that NITEK "has not charged NVT with patent infringement." (See, NITEK's Motion to Dismiss, Gerstman Decl., Ex. 12., first paragraph, second sentence). It is incontestable that at no time did NITEK or Mr. Gerstman indicate to NVT that NVT had a need for a license. Motion to Dismiss, Gerstman Decl., ¶ 3.

G. There Should Be No Collateral Estoppel.

On page 10 of its Opposition, NVT suggests that Judge Matz's uncertain finding of an actual controversy should be given collateral estoppel effect. However, NVT's own cases make it clear that collateral estoppel is inapplicable here.

Clearly, Judge Matz's finding of an actual controversy was uncertain, with Judge Matz stating that he "erred on the side of finding there is" an actual controversy; and he considered the finding of an actual controversy to be "marginal" and "weak". Significantly, Judge Matz's uncertain finding of an actual controversy was irrelevant to the decision dismissing the action. Either with or without the finding of an actual controversy, the action would have been dismissed.

It is well established that collateral estoppel requires a "prior adjudication of an issue in another action that is determined to be 'sufficiently firm' to be accorded preclusive effect." *Abbott Diabetes Care v. Roche Diagnostics*, 2007 U.S. Dist. LEXIS 34466, *37-38 (N.D. Cal. 2007) (collateral estoppel not applied because patent claim construction in preliminary injunction ruling was considered "tentative.). The Ninth Circuit has set forth several factors that should be considered when determining whether an order is sufficiently firm: "(1) whether the decision was not avowedly tentative; (2) whether the parties were fully heard; (3) whether the court supported its decision with a reasoned opinion; and (4) whether the decision was subject to appeal." *Ibid.*

Judge Matz's finding of a controversy was at best tentative. While the parties were indeed heard, the court did not support its decision with a reasoned opinion. Finally, the outcome is under appeal and the Federal Circuit has not been heard on the issue. All of this indicates that the finding of an actual controversy is not sufficiently firm and therefore should not be given preclusive effect.

Even NVT recognizes that for purposes of collateral estoppel, the decision must be "sufficiently firm" to be accorded conclusive effect (NVT's Opposition pg. 10, citing *Luben Indus. v. U.S.*, 707 F.2d 1037, 1040 (9th Cir. 1983). Judge Matz's uncertain decision regarding actual controversy was certainly not "sufficiently firm" nor was it "a critical and necessary part of the judgment in the earlier action." *Offshore Sportswear v. Vuarnet Int'l.*, 114 F.3d 848 (9th Cir. 1997).

III. THE FACTS AND CIRCUMSTANCES HERE ARE READILY DISTINGUISHABLE FROM MEDIMMUNE, SANDISK, SONY ELECTRONICS, TEVA PHARMACEUTICALS AND MICRON

The present facts and circumstances are clearly distinguishable from *MedImmune*. In *MedImmune* a patent licensee marketing a patented product sought to challenge patent validity without terminating an existing license. That is, the patent owner and the DJ plaintiff had an existing legal relationship and dispute over the terms of an existing contract/license. As the Supreme Court characterized the case, "Petitioner [DJ plaintiff and licensee] asserts that no royalties are owing because the... patent is invalid and not infringed; and alleges (without contradiction) a threat by respondents to enjoin sales if royalties are not forthcoming. The factual and legal dimensions of the dispute are well defined and, but for petitioner's continuing to make royalty payments, nothing about the dispute would render it unfit for judicial resolution." *MedImmune*, *supra*, 127 S. Ct. at 772.

In the instant matter, the factual and legal dimensions are not well defined. There is no dispute between NVT and NITEK. NVT is not a licensee of NITEK. There is no pre-existing legal relationship and NITEK has taken no action whatsoever to threaten NVT. Further, in contrast to *MedImmune*, NVT has not alleged that it is about to take or refrain from taking any

action based on the issuance of the '149 patent. NVT's main concern is that the '149 patent has issued and NITEK announced the issuance in a harmless press release.

Similarly, NVT's reliance on *SanDisk* is misplaced, as the facts in that case are readily distinguishable from the present case. NVT presents *SanDisk* as supporting a declaratory judgment "where a patentee [1] asserts rights under a patent [2] based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without a license under the patent, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights." NVT's Opposition, pg. 8, ll. 15-20 (emphasis added). NITEK has made NO assertion of rights under a patent. NITEK merely issued a broadly circulated harmless press release announcing that the patent had issued. NITEK is unaware of - and NVT has not identified - the requisite "certain identified ongoing or planned activity of [NVT]".

NVT further relies on *SanDisk* as supporting a DJ action despite a patentee's statement of no intent to sue. NVT's Opposition, pg. 11, II. 1-6. However, in stark contrast to the present case, in *SanDisk* the defendant particularly set out – claim by claim and product by product --how the plaintiff infringed defendant's patents. *SanDisk*, *supra*, 480 F.3d at 1375-1376 (Two of the patentee's licensing attorneys, and three patentee's technical experts performed the infringement analyses of SanDisk's products for SanDisk). The defendant there presented a slide show to the plaintiff detailing the infringement, followed by a four- to five-hour presentation during which the defendant identified and discussed the specific claims of each patent and alleged that they were infringed by SanDisk. The court referenced testimony that technical experts mapped elements of each of the allegedly infringed claims to the aspects of the accused SanDisk products alleged to practice the elements. In the instant matter NITEK has not discussed the '149 patent or any alleged infringement with NVT prior or even after the filing of this action. NITEK has stated unequivocally that it "has made no evaluation of, nor reached any determination that, a product of NVT is infringing any claim or claims of United States Patent No. 7,193,149." Motion to Dismiss, Third Decl. of Edward L. Polanek, ¶ 6.

"Guardian provided Sony with detailed

1 The other Federal Circuit cases (Micron, Sony Electronics, and Teva Pharmaceuticals) 2 cited by NVT are similarly misapplied. In Sony Electronics, the declaratory judgment defendant 3 Guardian had communicated to the declaratory judgment plaintiff Sony that certain identified 4 Sony products infringed Guardian's patents. 5 infringement analyses, which compared, on a limitation-by-limitation basis, a number of the 6 claims of the '158 and '160 patents to specific Sony products." Sony Electronics, v. Guardian 7 Media Technologies, 497 F.3d 1271, 1284 (Fed. Cir. 2007). Guardian claimed that there was no 8 controversy because Guardian was willing to engage in licensing negotiations. The court, 9 however, pointed out that "Guardian has explicitly identified the patents it believes that Sony 10 infringes, the relevant claims of those patents, and the relevant Sony products that it alleges infringe those patents." Ibid. Thus the Sony Electronics case is similar to the SanDisk case in 11 12 that in both cases the defendant pointed out how the plaintiff infringed the defendant's patents. 13 In the instant matter, NITEK has never claimed that NVT infringes NITEK's patent, has never 14 15

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charged NVT with infringement, has never determined whether any product of NVT is infringing, and has never indicated that NVT even needs a license. The present case is very clearly distinguishable over the Teva Pharmaceuticals case, cited by NVT. Teva Pharm., supra, 482 F.3d at 1330. In Teva Pharmaceuticals, the declaratory judgment defendant Novartis had sued Teva on its patents relating to the drug Famvir. Id. at 1334. Teva filed an Abbreviated New Drug Application ("ANDA") with the FDA for a generic substitute and Novartis brought an infringement suit against Teva on one of its five patents which were listed in the FDA Orange Book as covering various aspects of Famvir. *Ibid.* Thereafter, Teva brought a declaratory judgment action on the four remaining Teva patents. *Id.* at 1335. The court brought out how (1) by listing Novartis' five patents in the FDA Orange Book, Novartis represents that a claim of patent infringement could reasonably be asserted against a party manufacturing a generic version of Famvir; (2) that Teva had certified that it did not infringe the Famvir Orange Book patents or that the patents were invalid; (3) that there is a statute that permits an applicant to file a declaratory judgment action against the patent owner for

a declaratory judgment that the patent listed in the FDA orange book is invalid or will not be

infringed if the patent owner does not bring infringement action within 45 days; and (4) the pending infringement litigation on one of the five patents all taken together raises an actual controversy. *Id.* at 1341-1346. In the instant case, there are no factors remotely resembling any of these *Teva Pharmaceuticals* factors.

The present case is also clearly distinguishable over the *Micron* case, cited by NVT. *Micron Tech. v. Mosaid Techs.*, 518 F.3d 897 (Fed. Cir. 2008). In *Micron*, the declaratory judgment defendant Mosaid sent a warning letter strongly suggesting that Micron should license its technology. *Id.* at 899. Mosaid sent several follow-up letters. Mosaid then began filing patent infringement suits against its competitors and issued public statements reiterating its intent to pursue an aggressive licensing strategy. *Ibid.* Thus beginning in 2001, after receiving several threats from Mosaid, Micron (one of the four leading DRAM manufacturers) watched Mosaid sue each of the other leading DRAM manufacturers. Mosaid continued to make public statements which confirmed its intent to continue an aggressive licensing strategy. *Ibid.* The day after Micron filed a declaratory judgment action in the Northern District of California, Mosaid filed a patent infringement action against Micron in the Eastern District of Texas, clearly indicating a "controversy". *Id.* at 900. Obviously the facts of the instant case do not resemble the facts in the Micron case.

IV. IF THE COURT FINDS AN ARGUABLE "CASE OR CONTROVERSY" IT SHOULD EXERCISE ITS DISCRETION AND DISMISS THIS ACTION

A Court may exercise discretion in dismissing declaratory judgment actions in patent matters. *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 809 (Fed Cir. 1996) (overruled on separate grounds). The district court in *EMC* had considered whether the defendant's conduct gave rise to a reasonable apprehension of suit. It found that making that determination would be a significant undertaking and would involve a close question. *Id.* at 809. The court therefore decided that it would not further weigh proofs for jurisdictional purposes, but that it would exercise its discretion under the Declaratory Judgment Act. It declined to entertain the action. *Ibid.*

In upholding the district court's exercise of discretion to decline the suit, the Federal Circuit stated that "to entertain the declaratory judgment action would be inconsistent with the

purposes of the Declaratory Judgment Act. In particular, the [district] court found, to allow a declaratory judgment action to proceed under such circumstances would encourage parties who were negotiating with patentees to use the declaratory judgment procedure to improve their bargaining positions and to impede negotiations between patentees and other potential licensees or buyers." Id. at 810. V. **CONCLUSION**

In the instant matter, NVT has no realistic basis for establishing a case or controversy. NVT relies on "facts" including (i) double hearsay of conversations from unidentified sources (ii) equivocal statements from a person not a party to this litigation, and (iii) a press release distributed to the relevant industry that includes neither threats of enforcement nor accusations as to any NVT product. At its core, NVT offers not a single act by NITEK suggesting the existence of any case or controversy. NITEK undertook licensing negotiations at the request of NVT. NITEK never even indicated that NVT needed a license.

Although NVT has attempted to create a controversy, NITEK has worked to avoid controversy and there is none. This Court should grant NITEK's Motion to Dismiss for Lack of Subject Matter Jurisdiction or, in the alternative, decline to exercise jurisdiction because to entertain this declaratory judgment action would be inconsistent with the purposes of the Declaratory Judgment Act.

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SEYFARTH SHAW LLP

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Dated: September 2, 2008 By: /s/ Robert S. Niemann

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ROBERT S. NIEMANN, Cal. Bar No. 87973 560 Mission Street, 31st Floor San Francisco, California 94105

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Telephone: (415) 397-2823 Facsimile: (415) 397-8549 E-Mail: rniemann@seyfarth.com

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LEXSEE 2008 U.S. APP. LEXIS 17329

PRASCO, LLC, Plaintiff-Appellant, v. MEDICIS PHARMACEUTICAL CORPORATION and IMAGINATIVE RESEARCH ASSOCIATES, INC., Defendants-Appellees.

2007-1524

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2008 U.S. App. LEXIS 17329

August 15, 2008, Decided

PRIOR HISTORY: [*1]

Appeal from the United States District Court for the Southern District of Ohio in case no. 06-CV-313, Judge Michael R. Barrett.

Prasco, LLC v. Medicis Pharm. Corp., 2007 U.S. Dist. LEXIS 48302 (S.D. Ohio, July 3, 2007)

DISPOSITION: AFFIRMED.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff, the manufacturer of a competing generic benzoyl peroxide cleansing product, appealed from an order of the United States District Court for the Southern District of Ohio, that dismissed its declaratory judgment action against defendant, the holder of patents for similar cleansing products, which sought a declaration that its product did not infringe the patents in suit. The action was dismissed for lack of a case or controversy.

OVERVIEW: The district court found that, in the absence of any threat of an infringement suit by the patent holder, the court lacked subject matter jurisdiction to grant declaratory relief, because the generic manufacturer failed to show an imminent injury, and thus a case or controversy. The patent holder had marked products with the numbers of the four patents-in-suit to satisfy the public notice requirements of 35 U.S.C.S. § 287(a), and had previously brought an infringement suit against the generic manufacturer concerning a different cleanser product and an unrelated patent. The court of appeals concluded that there was no case or controversy because there was no definite and concrete dispute that touched the legal relations of these parties. The court concluded that under all the circumstances there was not a case or controversy within the meaning of U.S. Const. art. III or

the Declaratory Judgment Act. The patent holder had not taken a concrete position adverse to the generic manufacturer's. Had the district court reached the merits of this case, it would merely have provided an advisory opinion.

OUTCOME: The order dismissing the complaint for lack of jurisdiction was affirmed.

LexisNexis(R) Headnotes

Civil Procedure > Pretrial Judgments > Judgment on the Pleadings

[HN1] Where a case is dismissed by the district court on the pleadings, a reviewing court must take the facts in the complaint as true for purposes of appeal.

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > General Overview

Civil Procedure > Declaratory Judgment Actions > General Overview

[HN2] MedImmune, Inc. v. Genentech, Inc. reaffirmed that the proper test for subject matter jurisdiction in declaratory judgment actions is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Civil Procedure > Jurisdiction > General Overview Civil Procedure > Appeals > Standards of Review > De Novo Review

[HN3] An appellate court reviews issues of jurisdiction de novo.



Civil Procedure > Declaratory Judgment Actions > Federal Judgments > Scope [HN4] See 28 U.S.C.S. § 2201.

Civil Procedure > Justiciability > Case or Controversy Requirements > General Overview

Civil Procedure > Declaratory Judgment Actions > Federal Judgments > Scope

[HN5] The Declaratory Judgment Act, 28 U.S.C.S. § 2201, is not an independent basis for subject matter jurisdiction. Rather, it provides a remedy available only if the court has jurisdiction from some other source. Such jurisdiction is limited by U.S. Const. art. III, § 2, which restricts federal judicial power to the adjudication of "cases" or "controversies." The Declaratory Judgment Act's requirement of a case of actual controversy simply affirms that constitutional requirement, having long been interpreted as referring to any case and controversy that is justiciable under article III. "Cases of actual controversy" refers to controversies which are such in the constitutional sense. Thus, as long as the suit meets the case or controversy requirement of article III, a district court may have jurisdiction over a declaratory judgment action.

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Ancillary Claims

[HN6] Subject matter jurisdiction over actions for a declaratory judgment of patent non-infringement comes from 28 U.S.C.S. § 1338.

Civil Procedure > Justiciability > Case or Controversy Requirements > General Overview

[HN7] For there to be a case or controversy under U.S. Const. art. III, the dispute must be definite and concrete, touching the legal relations of parties having adverse legal interests, real and substantial, and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.

Civil Procedure > Justiciability > Case or Controversy Requirements > General Overview

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions

[HN8] There is no bright-line rule for determining whether an action satisfies the case or controversy requirement. To the contrary, the difference between an abstract question and a controversy contemplated by the Declaratory Judgment Act, 28 U.S.C.S. § 2201, is neces-

sarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy. Instead of a bright-line rule, the analysis must be calibrated to the particular facts of each case, with the basic standard being whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Civil Procedure > Justiciability > Case or Controversy Requirements > General Overview

[HN9] The United States Supreme Court has developed various more specific but overlapping doctrines rooted in the U.S. Const. art. III inquiry, which must be met for a controversy to be justiciable, including standing, ripeness, and a lack of mootness. As satisfying those doctrines represents the absolute constitutional minimum for a justiciable controversy, they are a helpful guide in applying the all-the-circumstances test.

Civil Procedure > Justiciability > Case or Controversy Requirements > General Overview

Patent Law > Infringement Actions > General Overview

[HN10] Prior to MedImmune, Inc. v. Genentech, Inc., the Federal Circuit generally required that a declaratory judgment plaintiff in a patent dispute demonstrate (1) conduct by the patentee that created a reasonable apprehension of suit on the part of the declaratory judgment plaintiff and (2) present activity by the declaratory judgment plaintiff that could constitute infringement or meaningful preparation to conduct potentially infringing activity. In MedImmune, the United States Supreme Court found that requiring a reasonable apprehension of suit conflicted with the court's precedent. While the Supreme Court rejected the reasonable apprehension of suit test as the sole test for jurisdiction, it did not completely do away with the relevance of a reasonable apprehension of suit. Rather, following MedImmune, proving a reasonable apprehension of suit is one of multiple ways that a declaratory judgment plaintiff can satisfy the more general all-the-circumstances test to establish that an action presents a justiciable article III controversy.

Civil Procedure > Pleading & Practice > Pleadings > Supplemental Pleadings

[HN11] Fed. R. Civ. P. 15(d) expressly allows for supplemental complaints to cure defects in the initial complaint.

Civil Procedure > Pleading & Practice > Pleadings > Supplemental Pleadings

[HN12] Supplemental pleadings can be used to cure subject matter jurisdiction deficiencies.

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > General Overview

[HN13] The proper focus in determining jurisdiction are the facts existing at the time the complaint under consideration was filed. When a plaintiff files a complaint in federal court and then voluntarily amends the complaint, courts look to the amended complaint to determine jurisdiction.

Civil Procedure > Pleading & Practice > Pleadings > Supplemental Pleadings

[HN14] It is Fed. R. Civ. P. 15(d), not Fed. R. Civ. P. 15(a), that governs supplemental complaints, even if the complaint is mislabeled as an amended complaint.

Civil Procedure > Pleading & Practice > Pleadings > Supplemental Pleadings

[HN15] Under Fed. R. Civ. P. 15(d), a district court has discretion to decide whether or not to allow a supplemental complaint so long as it does so upon reasonable notice and upon such terms as are just.

Civil Procedure > Justiciability > Case or Controversy Requirements > Immediacy

[HN16] The "immediacy and reality" inquiry can be viewed through the lens of standing. To satisfy standing, the plaintiff must allege (1) an injury-in-fact, that is, a harm that is concrete and actual or imminent, not conjectural or hypothetical, (2) that is fairly traceable to the defendant's conduct, and (3) redressable by a favorable decision. Absent an injury-in-fact fairly traceable to the patentee, there can be no immediate and real controversy.

Civil Procedure > Justiciability > Ripeness > General Overview

[HN17] The justicability issue can be viewed through one of the prongs of the ripeness doctrine, whether complained-of-conduct has an immediate and substantial impact on the plaintiff such that withholding court consideration would cause hardship to the plaintiff.

Civil Procedure > Declaratory Judgment Actions > Federal Judgments > General Overview

Patent Law > Infringement Actions > General Overview

[HN18] The existence of a patent is not sufficient to establish declaratory judgment jurisdiction. More is needed than knowledge of an adversely held patent. The mere existence of a potentially adverse patent does not cause an injury nor create an imminent risk of an injury; absent action by the patentee, a potential competitor is legally free to market its product in the face of an adversely-held patent.

Civil Procedure > Justiciability > Case or Controversy Requirements > Immediacy

[HN19] A fear of future harm that is only subjective is not an injury or threat of injury caused by the defendant that can be the basis of an article III case or controversy.

Civil Procedure > Justiciability > Standing > Injury in Fact

Patent Law > Infringement Actions > General Overview

[HN20] A purely subjective apprehension of a patent infringement suit is insufficient to satisfy the actual controversy requirement. Rather, it is the reality of the threat of injury that is relevant to the standing inquiry, not the plaintiff's subjective apprehensions.

Patent Law > Infringement Actions > General Overview

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions

[HN21] Jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee.

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Declaratory Judgment Actions

[HN22] Rather than a purely subjective fear or the mere existence of a potentially adverse patent alone, an alleged injury at the root of most justiciable declaratory judgment controversies in the patent context is a restraint on the free exploitation of non-infringing goods, or an imminent threat of such restraint.

Civil Procedure > Justiciability > Case or Controversy Requirements > Immediacy

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > General Overview

[HN23] A patentee can cause a real and immediate injury in a variety of ways, such as by creating a reasonable apprehension of an infringement suit, demanding the right to royalty payments, or creating a barrier to the regulatory approval of a product that is necessary for marketing.

Civil Procedure > Justiciability > Case or Controversy Requirements > General Overview

Patent Law > Infringement Actions > General Overview

[HN24] Where a party has actually been charged with infringement of the patent, there is, necessarily, a case or controversy adequate to support jurisdiction of a complaint. Where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an article III case or controversy will arise.

Patent Law > Infringement Actions > Defenses > Marking

[HN25] Under 35 U.S.C.S. § 287(a), a patentee's marking of its products with the applicable patent numbers serves as notice to the public that the goods are patented. Absent such a marking, the patentee is not entitled to receive damages for infringement that took place before the alleged infringer received actual notice of the infringement. The failure to mark a product under § 287(a) or to provide the requisite notice does not prohibit a patentee from bringing an infringement suit to obtain an injunction or damages occurring after the complaint was served. Nor does it prevent the patentee from demanding a licensing agreement, or otherwise interfering with a competitor's business.

Patent Law > Infringement Actions > General Overview

[HN26] Prior litigious conduct of a patentee is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy. However, one prior suit concerning different products covered by unrelated patents is not the type of pattern of prior conduct that makes reasonable an assumption that a patentee will also take action against a potential infringer regarding its new product.

Patent Law > Infringement Actions > Burdens of Proof

[HN27] Although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the case or controversy determination, it is not dispositive. A patentee has no obligation to spend the time and money to test a competitor's product nor to make a definitive determination, at the time and place of the competitor's choosing, that it will never bring an infringement suit. And the patentee's silence does not alone make an infringement action or other interference with the potential infringer's business imminent. Thus, though a patentee's failure to sign a covenant not to sue is one circumstance to consider in evaluating the totality of the circumstances, it is not sufficient to create an actual controversy; some affirmative actions by the patentee will also generally be necessary.

COUNSEL: William A. Rakoczy, Rakoczy Molino Mazzochi Siwik LLP, of Chicago, Illinois, argued for plaintiff-appellant. With him on the brief were Deanne M. Mazzochi and Amy D. Brody.

Matthew D. Powers, Weil, Gotshal & Manges LLP, of Redwood Shores, California, argued for defendants-appellees. On the brief were Barry J. Coyne, Reed Smith LLP, of Pittsburgh, Pennsylvania, and William J. McNichol, Jr., of Philadelphia, Pennsylvania. Of counsel were Elizabeth S. Weiswasser and Jennifer H. Wu, Weil, Gotshal & Manges LLP, of New York, New York.

JUDGES: Before GAJARSA, Circuit Judge, CLEVENGER, Senior Circuit Judge, MOORE, Circuit Judge.

OPINION BY: GAJARSA

OPINION

GAJARSA, Circuit Judge.

This is a patent case concerning the scope of our jurisdiction over declaratory judgment actions. Plaintiffappellant Prasco, LLC ("Prasco") brought a declaratory judgment action against defendants-appellees Medicis Pharmaceutical Corp. and Imaginative Research Associates, Inc. (collectively "the defendants"), seeking a declaration that one of its products did not infringe various patents owned by the defendants. [*2] The district court dismissed the action for lack of jurisdiction, concluding that Prasco's complaint failed to establish a case or controversy under Article III of the Constitution. Prasco LLC v. Medicis Pharm. Corp., No. 1:06cv313, 2007 U.S. Dist. LEXIS 26989, slip op. (S.D. Ohio Mar. 27, 2007) (Prasco I); Prasco LLC v. Medicis Pharm. Corp., No. 1:06cv313, 2007 U.S. Dist. LEXIS 48302, slip op. (S.D. Ohio July 3, 2007) (Prasco II). Because the district court was correct that under the standard affirmed in MedIm-

mune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 S. Ct. 764, 166 L. Ed. 2d 604 (2007), this action does not present an Article III case or controversy, we affirm.

I.

[HN1] As this case was dismissed on the pleadings, for the purposes of this appeal, we must take the facts in the complaint as true. Medicis markets a benzoyl peroxide cleansing product TRIAZ(R), which is marked as being covered by four patents, U.S. Patent Nos. 5,648,389 (the "'389 patent"); 5,254,334 (the "'334 patent"); 5,409,706 (the "'706 patent"); and 5,632,996 (the "'996 patent"). Prasco makes a generic benzoyl peroxide cleansing product OSCION TM, which it alleges will directly compete with Medicis' TRIAZ(R) product. The '389 patent is owned by Medicis; the '334, '706, and '996 patents are owned by Imaginative [*3] Research Associates and licensed to Medicis.

On May 26, 2006, Prasco filed the current action, requesting a declaratory judgment that OSCION TM did not infringe the '389, '334, '706, and '996 patents. \(^1\) At the time that Prasco filed its declaratory judgment action, it had not yet begun marketing OSCION TM, but had devoted substantial efforts to development and marketing plans.

1 The complaint does not challenge the validity of the four patents.

Prasco does not dispute that the defendants did not know about the existence of OSCION TM until the complaint was served. Rather, in its initial complaint, Prasco based its alleged Article III jurisdiction on two facts unrelated to the existence of OSCION TM: (1) Medicis' marking of TRIAZ(R) products with the numbers of the four patents-in-suit to satisfy the public notice requirements of 35 U.S.C. § 287 and (2) an infringement suit brought by Medicis against Prasco and another generic company in October 2005, concerning a different cleanser product, covered by an unrelated patent. ²

2 Imaginative Research Associates was not involved in the prior suit.

Defendants moved to dismiss the initial complaint on the grounds that a lack of case or controversy [*4] precluded subject matter jurisdiction. After the suit and the motion to dismiss were filed, Prasco sent a sample of OSCION TM and an ingredient list to Medicis and Imaginative Research Associates and requested a covenant not to sue under the four patents. The defendants did not sign the covenant not to sue and responded with a single sentence letter advising that they "do not plan to withdraw [their] motion to dismiss the complaint." Prasco subsequently filed a second complaint, styled an

"Amended Complaint" that included this post-filing conduct and the fact that it had begun to market OSCION TM. Defendants renewed their motion to dismiss.

Shortly after the Supreme Court issued its decision in MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 S. Ct. 764, 166 L. Ed. 2d 604 (2007), the district court granted the motion to dismiss the Amended Complaint. Prasco I, 2007 U.S. Dist. LEXIS 26989, slip op. at 10. [HN2] MedImmune reaffirmed that the proper test for subject matter jurisdiction in declaratory judgment actions is "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory [*5] judgment." MedImmune, 127 S. Ct. at 771. At the time of the district court's initial decision, this court had yet to issue a decision interpreting MedImmune, and notwithstanding the MedImmune Court's statement that the Federal Circuit's "reasonable apprehension of suit" test for determining subject matter jurisdiction in declaratory judgment actions contradicted earlier Supreme Court precedent, id. at 774 n.11, the district court applied the Federal Circuit's reasonable apprehension of suit test and found that Prasco had not alleged a case or controversy. Prasco I, 2007 U.S. Dist. LEXIS 26989, slip op. at 10. In a footnote, however, the court noted that even if MedImmune had overruled the reasonable apprehension of suit test, it would still conclude that there was no case or controversy because there was "no definite and concrete dispute that touches the legal relations of these parties." Prasco I. 2007 U.S. Dist. LEXIS 26989, *17 n.4.

Following this court's decision in Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp., 482 F.3d 1330 (Fed. Cir. 2007), which concluded that MedImmune had effectively overruled the reasonable apprehension of suit test, id. at 1339, the district court reconsidered its ruling pursuant to [*6] a Rule 59(e) motion, but declined to amend its decision. Prasco II, 2007 U.S. Dist. LEXIS 48302, slip op. at 8. The court concluded that under all the circumstances there was not an Article III case or controversy. Id. Prasco appeals the final judgment of dismissal. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II.

The only issue on appeal is whether the facts alleged in this case establish that there is a justiciable case or controversy within the meaning of the Declaratory Judgment Act and Article III of the Constitution. [HN3] We review issues of jurisdiction de novo. *Novartis*, 482 F.3d at 1335.

A.

Filed 09/02/2008

The Declaratory Judgment Act provides:

[HN4] In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201. [HN5] The Declaratory Judgment Act is not an independent basis for subject matter jurisdiction. Skelly Oil Co. v. Phillips Petroleum Co., 339 U.S. 667, 671-72, 70 S. Ct. 876, 94 L. Ed. 1194 (1950). Rather, it provides a remedy available only if the court has jurisdiction from some other source. Cat Tech LLC v. TubeMaster, Inc., 528 F.3d 871, 879 (Fed. Cir. 2008) [*7] (citing Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240, 57 S. Ct. 461, 81 L. Ed. 617 (1937)). Such jurisdiction is limited by Article III of the Constitution, which restricts federal judicial power to the adjudication of "Cases" or "Controversies." U.S. Const. art. III, § 2; Cat Tech LLC, 528 F.3d at 879. The Declaratory Judgment Act's requirement of "a case of actual controversy" simply affirms this Constitutional requirement, having long been interpreted as referring to any case and controversy that is justiciable under Article III. See Aetna Life Ins., 300 U.S. at 239-40 (explaining that the phrase "cases of actual controversy" refers "to controversies which are such in the constitutional sense"); see also MedImmune, 127 S. Ct. at 771. Thus, as long as the suit meets the case or controversy requirement of Article III, a district court may have jurisdiction over a declaratory judgment action. Novartis, 482 F.3d at 1340.3

> 3 Of course, meeting the requirements of Article III is necessary but not sufficient for district court jurisdiction. All other jurisdictional requirements, including a statutory basis for subject matter jurisdiction and personal jurisdiction over the defendant, must also be met. [HN6] Subject matter [*8] jurisdiction over actions for a declaratory judgment of patent non-infringement comes from 28 U.S.C. § 1338.

[HN7] For there to be a case or controversy under Article III, the dispute must be "definite and concrete, touching the legal relations of parties having adverse legal interests," "real and substantial," and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." MedImmune, 127 S. Ct. at 771 (quoting Aetna Life, 300 U.S. at 240-41). As the Supreme Court has recently reiterated, however, [HN8] there is no bright-line rule for determin-

ing whether an action satisfies the case or controversy requirement. Id. To the contrary, "[t]he difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy." Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273, 61 S. Ct. 510, 85 L. Ed. 826 (1941). Instead of a bright-line rule, "the analysis must be calibrated to the particular facts of each case," Cat Tech LLC, 528 F.3d at 879, [*9] with the basic standard being whether "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment," MedImmune, 127 S. Ct. at 771 (quoting Md. Cas. Co., 312 U.S. at 273); see also Caraco Pharms. Labs. Ltd. v. Forest Labs., 527 F.3d 1278, 1290 (Fed. Cir. 2008). While this standard can be analyzed directly, [HN9] the Supreme Court has also developed various more specific but overlapping doctrines rooted in the same Article III inquiry, which must be met for a controversy to be justiciable, including standing, ripeness, and a lack of mootness. See Caraco, 527 F.3d at 1291 (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992) (standing); Abbott Labs. v. Gardner, 387 U.S. 136, 149, 87 S. Ct. 1507, 18 L. Ed. 2d 681 (1967) (ripeness); and U.S. Parole Comm'n v. Geraghty, 445 U.S. 388, 397, 100 S. Ct. 1202, 63 L. Ed. 2d 479 (1980) (mootness)). As satisfying these doctrines represents the absolute constitutional minimum for a justiciable controversy, they can be a helpful guide in applying the all-thecircumstances test. Id.

[HN10] Prior to MedImmune, this circuit had generally required that a declaratory [*10] judgment plaintiff in a patent dispute demonstrate (1) conduct by the patentee that created a "reasonable apprehension" of suit on the part of the declaratory judgment plaintiff and (2) present activity by the declaratory judgment plaintiff that could constitute infringement or "meaningful preparation" to conduct potentially infringing activity. See, e.g., Glaxo Inc. v. Novopharm Ltd., 110 F.3d 1562, 1571 (Fed. Cir. 1997). However, in MedImmune, the Supreme Court found that requiring a reasonable apprehension of suit conflicted with the Court's precedent. MedImmune, 127 S. Ct. at 774 n.11. While the Supreme Court rejected the reasonable apprehension of suit test as the sole test for jurisdiction, it did not completely do away with the relevance of a reasonable apprehension of suit. Rather, following MedImmune, proving a reasonable apprehension of suit is one of multiple ways that a declaratory judgment plaintiff can satisfy the more general all-thecircumstances test to establish that an action presents a

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justiciable Article III controversy. Caraco, 527 F.3d. at 1291.4

> The second prong of the old test, whether there has been potentially infringing activity or meaningful preparation [*11] to conduct potentially infringing activity, "remains an important element in the totality of circumstances which must be considered in determining whether a declaratory judgment is appropriate." Cat Tech LLC, 528 F.3d at 880. This element is not in contention here, however, as according to the complaint, Prasco is currently making and selling OSCION TM.

B.

As an initial matter, the parties dispute whether the allegations in Prasco's Amended Complaint that concern actions taken after the filing of the initial complaint can be used to establish subject matter jurisdiction. Because the Amended Complaint included allegations regarding events that happened after the first complaint, technically it is a supplemental complaint, not an "amended complaint." See Fed. R. Civ. P. 15(d) (allowing a party to "serve a supplemental pleading setting forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented"); 6A Wright & Miller, Federal Practice and Procedure § 1504, at 184 ("Parties and courts occasionally confuse supplemental pleadings with amended pleadings and mislabeling is common. However, these misnomers are not of any significance [*12] and do not prevent the court from considering a motion to amend or supplement under the proper portion of *Rule 15.*").

[HN11] Rule 15(d) expressly allows for supplemental complaints to "cure" defects in the initial complaint. Fed. R. Civ. P. 15(d) ("Permission [to serve a supplemental pleading] may be granted even though the original pleading is defective in its statement of a claim for relief or defense."). The Supreme Court has confirmed that[HN12] supplemental pleadings can be used to cure subject matter jurisdiction deficiencies. See Mathews v. Diaz, 426 U.S. 67, 75, 96 S. Ct. 1883, 48 L. Ed. 2d 478 (1976) (explaining that there was "little difficulty" in a party's failure to file an application that was a "nonwaivable condition of jurisdiction" until after he was joined in the action because "[a] supplemental complaint in the District Court would have eliminated this jurisdictional issue"); see also 6A Wright & Miller, Federal Practice and Procedure § 1505, at 191 (explaining that, prior to the 1963 amendment to Rule 15(d), some courts had not allowed curing of defects through supplemental complaints, but that the addition of the second sentence to 15(d) in 1963 removed "any uncertainty on the point").

Thus, while "[1]ater events [*13] may not create jurisdiction where none existed at the time of filing," [HN13] the proper focus in determining jurisdiction are "the facts existing at the time the complaint under consideration was filed." GAF Bldg. Materials Corp. v. Elk Corp., 90 F.3d 479, 483 (Fed. Cir. 1996) (emphasis added) (quoting Arrowhead Indus. Water, Inc. v. Ecolochem Inc., 846 F.2d 731, 734 n.2 (Fed. Cir. 1988)); see also Rockwell Int'l Corp. v. United States, 549 U.S. 457, 127 S. Ct. 1397, 1409, 167 L. Ed. 2d 190 (2007) ("[W]hen a plaintiff files a complaint in federal court and then voluntarily amends the complaint, courts look to the amended complaint to determine jurisdiction."); Connectu LLC v. Zuckerberg, 522 F.3d 82 (1st Cir. 2008). As the district court accepted Prasco's Amended Complaint, it is the Amended Complaint that is currently under consideration, and it is the facts alleged in this complaint that form the basis for our review. 5

> The district court seemed to assume that Prasco had the right to file its Amended Complaint "as a matter of course" under Federal Rule of Civil Procedure 15(a). Prasco I, 2007 U.S. Dist. LEXIS 26989, *9. This is incorrect.[HN14] It is Rule 15(d), not Rule 15(a), that governs supplemental complaints, even if the complaint is [*14] mislabeled as an amended complaint. [HN15] Under Rule 15(d) the district court had discretion to decide whether or not to allow Prasco's supplemental complaint so long as it did so "upon reasonable notice and upon such terms as are just." Defendants conceded at oral argument that it was within the district court's discretion to accept Prasco's Amended Complaint, and they have never argued that the district court's arguable failure to acknowledge its own discretion was an abuse of discretion. Accordingly, any challenge to the district court's decision to accept the Amended Complaint is waived. Moreover, as we conclude that there is no subject matter jurisdiction even when the additional facts alleged in the Amended Complaint are considered, any such error would be harmless.

C.

Considering the totality of the circumstances, Prasco has not alleged a controversy of sufficient "immediacy and reality" to create a justiciable controversy. [HN16] This "immediacy and reality" inquiry can be viewed through the lens of standing. To satisfy standing, the plaintiff must allege (1) an injury-in-fact, i.e., a harm that is "concrete' and actual or imminent, not 'conjectural' or 'hypothetical,'" (2) that is "fairly [*15] traceable" to the defendant's conduct, and (3) redressable by a favorable decision. Caraco, 527 F.3d at 1291 (quoting Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 102-03, 118 S. Ct. 1003, 140 L. Ed. 2d 210 (1998)); see also Daimler-Chrysler Corp. v. Cuno, 547 U.S. 332, 342, 126 S. Ct. 1854, 164 L. Ed. 2d 589 (2006). Absent an injury-in-fact fairly traceable to the patentee, there can be no immediate and real controversy. ⁶

6 [HN17] This justicability problem can also be viewed through one of the prongs of the ripeness doctrine, whether the complained-of-conduct has an "immediate and substantial impact" on the plaintiff such that withholding court consideration would cause hardship to the plaintiff. Caraco, 527 F.3d at 1294-95 (quoting Gardner v. Toilet Goods Ass'n, 387 U.S. 167, 171, 87 S. Ct. 1526, 18 L. Ed. 2d 704 (1967)); see also Hillblom v. United States, 896 F.2d 426, 430 (9th Cir. 1990). In the circumstances of this case, the underlying inquiry, rooted in the requirement that Article III courts cannot issue advisory opinions, is the same regardless of whether labeled standing, ripeness, or the requirement that the controversy have "sufficient immediacy and reality." See MedImmune, 127 S. Ct. at 772 n.8 (explaining that the justicability problem at issue could be described in terms [*16] of standing or ripeness and that "standing and ripeness boil down to the same question in this case").

As Prasco acknowledges, *MedImmune* does not change our long-standing rule that [HN18] the existence of a patent is not sufficient to establish declaratory judgment jurisdiction. *See Capo, Inc. v. Dioptics Med. Prods. Inc., 387 F.3d 1352, 1355 (Fed. Cir. 2004)* ("More is needed than knowledge of . . . an adversely held patent."). The mere existence of a potentially adverse patent does not cause an injury nor create an imminent risk of an injury; absent action by the patentee, "a potential competitor . . . is legally free to market its product in the face of an adversely-held patent." ⁷ *Novartis, 482 F. 3d at 1345*.

7 The situation is different in the highly-regulated pharmaceutical context, in which a manufacturer is not permitted to market a drug without FDA approval. See generally Caraco, 527 F.3d at 1278.

Prasco argues that a case and controversy has nevertheless been created because Medicis has caused Prasco to suffer an actual harm--namely, "paralyzing uncertainty" from fear that Medicis will bring an infringement suit against it. Appellant's Br. 23. As Prasco admitted at oral argument, however, [*17] any uncertainty has not been paralyzing. To the contrary, notwithstanding this lawsuit, Prasco has launched its OSCION TM product.

More importantly, the Supreme Court has emphasized that [HN19] a fear of future harm that is only subjective is not an injury or threat of injury caused by the defendant that can be the basis of an Article III case or controversy. City of L.A. v. Lyons, 461 U.S. 95, 103 S. Ct. 1660, 75 L. Ed. 2d 675 (1983); see also Indium Corp. of Am. v. Semi-Alloys, Inc., 781 F.2d 879, 883 (Fed. Cir. 1985) ("A [HN20] purely subjective apprehension of an infringement suit is insufficient to satisfy the actual controversy requirement."). Rather, "it is the reality of the threat of . . . injury that is relevant to the standing inquiry, not the plaintiff's subjective apprehensions." Lyons, 461 U.S. at 107 n.8 (emphasis in original); see also Laird v. Tatum, 408 U.S. 1, 13-14, 92 S. Ct. 2318, 33 L. Ed. 2d 154 (1972) ("Allegations of a subjective 'chill' are not an adequate substitute for a claim of specific present objective harm or a threat of specific future harm; 'the federal courts established pursuant to Article III of the Constitution do not render advisory opinions.""). Although MedImmune clarified that an injury-in-fact sufficient to create an actual [*18] controversy can exist even when there is no apprehension of suit, it did not change the bedrock rule that a case or controversy must be based on a real and immediate injury or threat of future injury that is caused by the defendants--an objective standard that cannot be met by a purely subjective or speculative fear of future harm. Thus, as we explained post-MedImmune, [HN21] "jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." SanDisk, 480 F.3d at 1380-81.

[HN22] Rather than a purely subjective fear or the mere existence of a potentially adverse patent alone, the alleged injury at the root of most justiciable declaratory judgment controversies in the patent context is a "restraint on the free exploitation of non-infringing goods," or an imminent threat of such restraint. Caraco, 527 F.3d at 1291 (quoting Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc., 148 F.3d 1355, 1360 (Fed. Cir. 1998)).

[HN23] A patentee can cause such an injury in a variety of ways, for example, by creating a reasonable apprehension of an infringement [*19] suit, e.g., Arrowhead Indus. Water, 846 F.2d at 737, demanding the right to royalty payments, e.g., MedImmune, 127 S. Ct. at 777, or creating a barrier to the regulatory approval of a product that is necessary for marketing, e.g., Caraco, 527 F.3d at 1292-94. See also Arrowhead Indus. Water, 846 F.2d at 735 (describing the type of "sad and saddening scenario" that led to enactment of the Declaratory Judgment Act in which the "patent owner attempts extrajudicial patent enforcement with scare-the-customer-and-run

tactics that infect the competitive environment of the business community with uncertainty and insecurity").

Prasco does not allege that defendants had actually restrained its right to freely market OSCION TM at the time the supplemental complaint was filed. Rather, it is the threat of future injury that forms the basis for Prasco's complaint. Thus, there can be no controversy without a showing that this threat was real, imminent, and traceable to defendants.

Taking all the facts into account, Prasco has not met this threshold burden of proving an immediate and real controversy. Important to the totality of the circumstances analysis in the instant case is that which has not occurred. [*20] Generally, the Supreme Court has affirmed declaratory judgment jurisdiction when "the parties had taken adverse positions with regard to their obligations, each side presenting a concrete claim of a specific right" prior to the suit. SanDisk Corp., 480 F.3d at 1379 (citing Aetna Life Ins., 300 U.S. at 240-41 and Md. Casualty, 312 U.S. at 272); see also MedImmune, 127 S. Ct. at 772-77 (concluding that declaratory judgment jurisdiction was proper in the context of a patent licensing agreement when the patentee claimed a right to royalties under the licensing agreement, and the licensee asserted that no royalties were owing because the patent was invalid and not infringed); Altvater v. Freeman, 319 U.S. 359, 365, 63 S. Ct. 1115, 87 L. Ed. 1450, 1943 Dec. Comm'r Pat. 833 (1943) ("[T]he requirements of case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim."); Cardinal Chem. Co. v. Morton Int'l, 508 U.S. 83, 96, 113 S. Ct. 1967, 124 L. Ed. 2d 1 (1993) ("If . . . [HN24] a party has actually been charged with infringement of the patent, there is, necessarily, a case or controversy adequate to [*21] support jurisdiction of a complaint"). And we have held that "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise." SanDisk, 480 F.3d at 1381.

In contrast, here the defendants have not accused Prasco of infringement or asserted any rights to OSCION TM, nor have they taken any actions which imply such claims. Instead, all we have before us is Prasco's allegation that its product does *not* infringe the defendants' patents. The defendants' lack of any "concrete claim of a specific right" is an important factor weighing against a finding of an actual controversy, particularly given that there has been no actual injury. The lack of any evidence that the defendants believe or plan to assert that the

plaintiff's product infringes their patents creates a high barrier to proving that Prasco faces an imminent risk of injury. 8 Moreover, not only have the defendants not taken a concrete position adverse to Prasco's, but they also have taken no affirmative actions at all related [*22] to Prasco's current product.

8 In addition, the lack of clearly delineated, adverse positions by the parties diminishes the "definite[ness] and concrete[ness]" of any potential controversy and its fitness for current judicial resolution. Prasco asks this court to find that its benzoyl peroxide product does not infringe any of the 71 claims of the four patents, each of which have additional limitations beyond benzoyl peroxide being an active ingredient. We have no way of knowing which if any of these claims defendants could or might assert against Prasco.

None of the facts on which Prasco relies overcome the complete lack of evidence of a defined, preexisting dispute between the parties concerning OSCION TM. First, Prasco relies on Medicis' marking of its products with the four patents-in-suit, consistent with the requirements of 35 U.S.C. § 287(a). [HN25] Under § 287(a), a patentee's marking of its products with the applicable patent numbers serves as notice to the public that the goods are patented. Absent such a marking, the patentee is not entitled to receive damages for infringement that took place before the alleged infringer received actual notice of the infringement. Id. The failure to [*23] mark a product under $\oint 287(a)$ or to provide the requisite notice does not prohibit a patentee from bringing an infringement suit to obtain an injunction or damages occurring after the complaint was served. Id. Nor does it prevent the patentee from demanding a licensing agreement, or otherwise interfering with a competitor's business. Indeed, in the one infringement suit that Medicis has brought against Prasco--regarding unrelated products and unrelated patents--it appears that Medicis' products were not marked with the patents alleged to be infringed. Conversely, Medicis' decision to mark its products with the applicable patents provides little, if any, evidence that it will ever enforce its patents. And in particular, Medicis' decision to mark its products, prior to any knowledge of Prasco's OSCION TM product, is irrelevant to the question of whether Medicis' believes OSCION TM infringes the applicable patents or will attempt to interfere with Prasco's business on the basis of an allegation of infringement. Thus, Medicis' marking of its competing products pursuant to $\oint 287(a)$ is not [*24] a circumstance which supports finding an imminent threat of harm sufficient to create an actual controversy.

Second, Prasco argues that Medicis' past history of enforcing patent rights to protect its "core products" sup-

ports a finding of a case or controversy. In particular, Prasco alleges that Medicis' infringement suit against Prasco and another generic company in October 2005 demonstrates a genuine risk that the defendants will also attempt to enforce its patents against Prasco. 9 [HN26] Prior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy. However, one prior suit concerning different products covered by unrelated patents is not the type of pattern of prior conduct that makes reasonable an assumption that Medicis will also take action against Prasco regarding its new product. See Indium Corp., 781 F.2d at 883. Accordingly, Medicis' prior suit premised on other patents cannot alone create a real and immediate controversy, and it is entitled to only minimal weight in analyzing whether such a controversy has been created. 10

- 9 Prasco also argues in its briefs that Medicis has brought other suits against [*25] competitors. However, such conduct is not clearly alleged in its complaint. Accordingly, we will not consider it.>
- 10 Moreover, the prior suit has no relevance to whether there is a case or controversy with Imaginative Research Associates, as Imaginative Research Associates was not a party to the prior suit.

Third, Prasco places significant weight on Medicis' and Imaginative Research Associates' failure to sign covenants not to sue after Prasco sent them samples of OSCION TM in the wake of their initial motion to dismiss. We have explained that [HN27] "although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, it is not dispositive." BP Chems. v. Union Carbide Corp., 4 F.3d 975, 980 (Fed. Cir. 1993). A patentee has no obligation to spend the time and money to test a competitors' product nor to make a definitive determination, at the time and place of the competitors' choosing, that it will never bring an infringement suit. And the patentee's silence does not alone make an infringement action or other interference with the plaintiff's business imminent. Thus, though a defendant's failure to sign a covenant not to sue

is one circumstance [*26] to consider in evaluating the totality of the circumstances, it is not sufficient to create an actual controversy--some affirmative actions by the defendant will also generally be necessary. ¹¹

11 Conversely, we have held that in certain situations signing a covenant not to sue is also not sufficient to defeat declaratory judgment jurisdiction if signing the covenant does not negate the underlying injury. See Caraco, 527 F.3d at 1296-97

Here, where Prasco has suffered no actual present injury traceable to the defendants, and the defendants have not asserted any rights against Prasco related to the patents nor taken any affirmative actions concerning Prasco's current product, one prior suit concerning unrelated patents and products and the defendants' failure to sign a covenant not to sue are simply not sufficient to establish that Prasco is at risk of imminent harm from the defendants and that there is an actual controversy between the parties of sufficient immediacy and reality to warrant declaratory judgment jurisdiction. Although we understand Prasco's desire to have a definitive answer on whether its products infringe defendants' patents, were the district court to reach the merits [*27] of this case, it would merely be providing an advisory opinion. This is impermissible under Article III. 12

12 Prasco had sued only for a declaratory judgment of non-infringement. We thus have no opportunity to consider whether similar facts would be sufficient to establish jurisdiction if, instead, Prasco had conceded infringement and was only arguing invalidity.

III.

Considering the totality of the circumstances, Prasco has failed to establish a case or controversy under Article III. Therefore, the judgment of the district court dismissing the case for lack of jurisdiction is affirmed.

AFFIRMED